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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Licata & Tyrrell P.C.  
Jane Massey Licata, Esquire  
66 E. Main Street  
Marlton, NJ 08053

EXAMINER

TON, THAIAN N

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 01/29/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/918,396

Applicant(s)

KENNEDY ET AL.

Examiner

Thaian N. Ton

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 22 and 23 is/are pending in the application.
- 4a) Of the above claim(s) 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Claims 22 and 23 are pending. Claim 22 is under current examination.

#### *Election/Restrictions*

Applicant's election with traverse of Group I [claim 22] in Paper No. 11 is acknowledged. The traversal is on the ground(s) that the search of Group I would, of necessity include a search of Group II because the claim of Group II is drawn to a method of using the same inhibitor. Applicants further argue that both Groups represent alternate embodiments utilizing inhibitors identified from knock out mice that is the subject matter of this application, wherein the mouse has altered fat and glucose metabolism when compared with wild-type mice. Applicants argue that the assertion that the two claims are mutually exclusive and independent methods is not consistent with the mechanism provided by the Applicant, that no savings of PTO resources will be achieved by enforcing the requirement, and that Applicants request the consideration of the grouping of the claims to be consistent with the IPER of the PCT application upon which this national application is based, 2<sup>nd</sup> ¶ of the Response. This is not found persuasive because the claims are directed to methods of treating obesity or methods of treating Type II diabetes, by administration of an inhibitor of PTP-1B to an individual. These methods are mutually exclusive and independent methods, because they require different considerations and a separate and materially different protocol. Although the

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methods require administration of an inhibitor of PTP-1B, the claims as broadly written, encompass inhibitors of PTP-1B, which are not disclosed nor claimed. Furthermore, with regard to Applicants' request that the instant application be grouped as consistent with the IPER of the PCT upon which, "this national stage application is based" [see p. 2, 2<sup>nd</sup> ¶, last sentence of the Response], it is noted that this case is a divisional of 09/744,383 [which is a national stage application]. It is noted that the restriction of the '383 is consistent with the restriction of the instant application. Furthermore, MPEP §802 states that

(a) Two or more independent and distinct inventions may not be claimed in one national application, except that more than one species of an invention, not to exceed a reasonable number, may be specifically claimed in different claims in one national application, provided the application also includes an allowable claim generic to all the claimed species and all the claims to species in excess of one are written in dependent form (§ 1.75) or otherwise include all the limitations of the generic claim. [37 CFR 1.141.]

The instant case does not claim more than one species of an invention. Accordingly, the requirement is still deemed proper and is therefore made FINAL.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

*Drawings*

The drawings filed on October 11, 2001 are approved.

*Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 22 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111 (Fed. Cir. 1991), clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d at 1117. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed. *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d at 1116.

The invention is directed to a method of treating obesity by administering inhibitors of PTP-1B. However, the specification does not provide sufficient

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description of the chemical structure of PTP-1B inhibitors to demonstrate possession of the method at the time of filing. A person of ordinary skill in the art, as referred to in Vas-Cath, reading the claim would not recognize that Applicant had invented the method because there is no disclosure of chemical structure of even one inhibitor of PTP-1B.

The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which are not conventional in the art **as of Applicants effective filing date**. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics (as it relates to the claimed invention as a whole) such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641, 1646 (1998).

A review of claim 22 indicates that the inhibitor of PTP-1B is critical and essential to the practice of the claim. Thus, the specification must fully describe such inhibitors, especially as none were known at the time of filing. The specification teaches methods for the identification of inhibitors of the enzymatic activity of PTP-1B [see pp. 13-14]. However, the skilled artisan cannot envision the detailed chemical structure of all the inhibitors of PTP-1B enzymatic activity, as encompassed by the claims, and therefore, conception is not achieved until

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reduction to practice has occurred. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of identifying it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991).

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. The instant claim requires an inhibitor but there is no description of inhibitors of PTP-1B, which would indicate possession by Applicant at the time of filing.

Therefore, as no inhibitors of the enzymatic activity of PTP-1B have been described, the claim does not meet the written description provision of 35 U.S.C. §112, first paragraph.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim 22 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claimed invention is directed to a method of treating obesity comprising administering an inhibitor of the enzymatic activity of PTP-1B.

The claimed invention is not enabling because the specification fails to provide teachings or guidance with particularity for any specific inhibitors that would be capable of treating obesity, as required by the claims. The specification does not teach or provide guidance with regard to what substances would function as an inhibitor of PTP-1B enzymatic activity and would be capable of treating obesity. Further, the specification fails to teach or provide guidance for administering such an inhibitor, such that serious injury would not occur. It is well-known in the art that the substrates of PTP-1B, insulin receptor, is involved in more than just sugar uptake. Furthermore, it is well-known in the art that weight reduction is not regarded as predictable.

Accordingly, in view of the lack of teaching or guidance provided by the specification with regard to specific inhibitors of PTP-1B enzymatic activity that would be capable of treating obesity, the lack of teachings or guidance provided by the specification for administration of such an inhibitor which would not cause grievous harm to an individual, as well as the unpredictable state of the art of weight reduction, it would have required undue experimentation for one of skill in the art to make and/or use the claimed invention.



*Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is drawn to a method treating obesity comprising administering an inhibitor of the enzymatic activity of PTP-1B to an obsess mammal, but no clear and defined steps are recited. While minute details are not required in method claims, at least the basic steps must be recited in a positive, active fashion. See Ex Parte Erlich, 3 USPQ2d, p. 1011 (Bd. Pat. App. Int. 1986). For example, Furthermore, the term "inhibitor" is vague and indefinite, as the specific structure of any particular inhibitor could not be envisioned.

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*Conclusion*

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thaian N. Ton whose telephone number is (703) 305-1019. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the examiner be unavailable, inquiries should be directed to Deborah Reynolds, Supervisory Primary Examiner of Art Unit 1632, at (703) 305-4051. Any administrative or procedural questions should be directed to William Phillips, Patent Analyst, at (703) 305-3482. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

TNT

Thaian N. Ton  
Patent Examiner  
Group 1632

*Deborah Crouch*

DEBORAH CROUCH  
PRIMARY EXAMINER  
GROUP 1800-1630